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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,455

06/26/2003

Paula J. Bates

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EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,455

Applicant(s)

BATES ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16,43,44,46,47 and 51-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16,43,44,46,47 and 51-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/7/07.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/7/07 has been entered.
2. Claims 13-16, 43-44, 46-47 and 51-62 are pending and are being acted upon in this Office Action.
3. Claim 44 is objected to because the phrase "the preparing further comprises" is missing the word "step". It is suggested that the claim be amended to recite "The method of claim 13, wherein the preparing step further comprises..."
4. Claim 46 is objected to because the phrase "the antibody *comprises* an anti-nucleolin monoclonal antibody" should have been "the antibody is an anti-nucleolin monoclonal antibody".
5. Claim 47 is objected to because the phrase "the antibody *comprises* an anti-nucleolin polyclonal antibody" should have been "the antibody is an anti-nucleolin polyclonal antibody".
6. Claim 56 is objected to because the phrase "the preparing further comprises" is missing the word "step". It is suggested that the claim be amended to recite "The method of claim 51, wherein the preparing step further comprises..."
7. Claim 57 is objected to because the phrase "the antibody *comprises* an anti-PARP-1 monoclonal antibody" should have been "the antibody is an anti-PARP-1 monoclonal antibody".
8. Claim 58 is objected to because the phrase "the antibody *comprises* an anti-PARP-1 polyclonal antibody" should have been "the antibody is an anti-PARP-1 polyclonal antibody".

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 13-16, 43-44, 46-47 and 51-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because the method is incomplete; merely reacting an antibody that binds specifically to nucleolin will not achieve the goal set forth in the preamble of detecting excessive apoptosis. Further, there is no nexus between reacting antibody binding to nucleolin and detecting apoptotic bodies. Finally, method step should be in active voice rather than passive voice. It is suggested that claim 13 be amended to recite "A method of detecting excessive apoptosis in a subject, comprising: preparing a blood sample from said subject, removing cells from said sample, reacting said sample with an antibody that binds specifically to nucleolin, and detecting the binding of said antibody to nucleolin in the apoptotic bodies of said sample is indicative of excessive apoptosis in said subject."

Claim 51 is indefinite because the method is incomplete; merely reacting an antibody that binds specifically to poly(ADP-ribose) polymerase (PARP-1) will not achieve the goal set forth in the preamble of detecting excessive apoptosis. Further, there is no nexus between reacting antibody binding to nucleolin and detecting apoptotic bodies. Finally, method step should be in active voice rather than passive voice. It is suggested that claim 51 be amended to recite "A method of detecting excessive apoptosis in a subject, comprising: preparing a blood sample from said subject, removing cells from said sample, reacting said sample with an antibody that binds specifically to poly(ADP-ribose) polymerase (PARP-1), and detecting the binding of said antibody to PARP-1 in the apoptotic bodies of said sample is indicative of excessive apoptosis in said subject."

The remaining claims are rejected for depending from indefinite claims 13 and 51.

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be

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left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

13. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Patent Examiner

Technology Center 1600

August 3, 2007